(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
2 June 2005 (02.06.2005)

PCT

(10) International Publication Number
WO 2005/048815 A2

(51) International Patent Classification⁷: A61B

(21) International Application Number: PCT/US2004/037804

(22) International Filing Date: 12 November 2004 (12.11.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/519,881 13 November 2003 (13.11.2003) US

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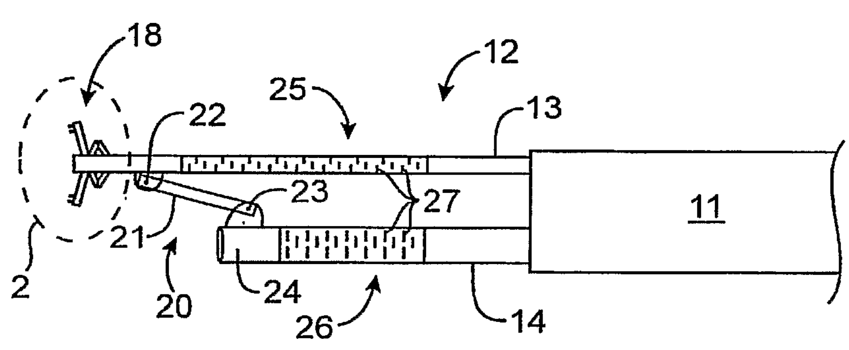
(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) **Title:** APPARATUS AND METHODS FOR ENDOSCOPIC SUTURING



(57) Abstract: Apparatus and methods for endoscopic suturing are described herein. A distal tip of the endoscopic device engages the tissue and then approximates the engaged tissue to form a tissue fold. A needle body positioned within a flexible catheter is deployed into or through the newly created tissue fold where it is then detached or released from the endoscopic device. The needle body has a length of suture which depends therefrom and can be used to secure the tissue fold. The entire endoscopic device or its tissue engaging assembly can then be rotated relative to the tissue fold while maintaining engagement with the tissue to maneuver the flexible catheter to the opposing side of the penetrated tissue fold. This procedure can be repeated any number of times to create an interrupted, continuous, or running suture to secure the tissue fold.

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APPARATUS AND METHODS FOR ENDOSCOPIC SUTURING

BACKGROUND OF THE INVENTION

[0001] Field of the Invention. The present invention relates to apparatus and methods for endoscopically forming and suturing tissue. More particularly, the present invention relates to apparatus and methods for endoscopically forming tissue folds and continuously suturing those folds.

[0002] Various devices and methods for grasping free ends or lengths of suture and passing the suture material through tissue are known. One method generally involves attaching a suture end to a needle and passing the needle through the tissue using a needle manipulating device. Once passed through the tissue, another device is typically employed to retrieve or otherwise manipulate the needle and suture.

[0003] Other methods generally utilize sharpened needle tips which are configured to retain a suture. The needle tip is then able to penetrate the tissue and leave the suture end on the far side of the tissue where it can be grasped for further manipulation. Such grasping mechanisms generally employ various configurations such as the use of wire-like hooking elements, looped wires, etc. Some devices employ suture grasping elements, such as forceps jaws, with sharpened tips to grasp and pass the suture material.

[0004] However, many of the conventional devices have limitations in applications such as closed surgery, especially arthroscopic or laparoscopic surgery, where space and visibility constraints at the surgical site render it difficult to fully extend a suture grasping device to easily grasp a suture. Moreover, many of the devices are constrained to regions within the body accessible via straight-line access. This is typically due to the rigidity of the tool shaft upon which the graspers or needles are employed.

[0005] Furthermore, because of the typical size and rigidity of the tool, such a suture passing instrument is typically inserted within a patient as a separate tool which occupies valuable space. Additionally, other tools are typically needed to facilitate the manipulation of the suture material through the tissue.

BRIEF SUMMARY OF THE INVENTION

[0006] In forming or securing folds of tissue, e.g., in the gastrointestinal (GI) tract such as the stomach of a patient, tissue folds may be formed to treat various conditions such as obesity. Such treatments may be effected via an endoscopic device designed to engage a tissue wall, create one or more tissue folds, and secure the tissue fold(s) with tissue anchors and/or suture.

[0007] One such endoscopic device described herein may have a primary grasper at a distal tip of the endoscopic device configured to engage the tissue and then approximate the engaged tissue to a proximal position relative to the catheter tip, thereby providing a uniform plication of predetermined size. A needle body detachably or removably positioned within a flexible catheter or launch tube may be deployed from the launch tube such that it passes at least partially within or entirely through the fold formed by the approximated tissue. The needle body may also have a length of suture attached thereto for passage through the tissue fold. Once the needle body has been penetrated into or through the tissue fold, it may be detached or released from the endoscopic device via a secondary needle grasper. A description of one or more endoscopic devices which may be utilized to initially form the one or more tissue folds may be seen in further detail in U.S. Pat. App. Serial No. 10/735,030 filed Dec. 12, 2003, which is incorporated herein by reference in its entirety.

[0008] The needle body itself may generally be configured as a needle having one or two tapered piercing ends on opposing sides of the needle body. A suture attachment point, e.g., an eyelet or opening, may be defined along the needle body and serve as an attachment point for a length of suture. Alternatively, an expandable anchor may also be positioned within a needle body for passage through tissue. Once free of the tissue, the anchor may be deployed from the needle body for placement against the tissue. Other variations of the needle body and grasper may be seen in further detail in U.S. Pat. App. Serial No. 10/989,684 filed July 23, 2004, which is incorporated herein by reference in its entirety.

[0009] In operation, once the needle body has been advanced through or at least partially through the tissue fold, the needle body may be released by the secondary needle grasper and the entire endoscopic device or its tissue engaging assembly may then be rotated relative to the opposite side of the tissue fold, i.e., on the side of the tissue where the needle body exits the tissue fold, while maintaining engagement with the tissue via the primary grasper to maneuver the catheter or launch tube to the opposing side of the penetrated tissue fold. The

rotatable primary grasper may keep its grasp on the tissue fold to maintain a position of the device relative to the tissue fold and needle body. The length of suture remains attached to the needle body and is routed through the tissue passage created by the needle body.

[0010] The secondary grasper may then be used to grasp onto the needle body and while holding the needle body, the entire apparatus may again be rotated to realign the needle launch tube back to the other side of the tissue fold. Once the needle body has been desirably positioned, it may again be manipulated to align the catheter distal tip transversely relative to the tissue fold which may again be pierced by advancing the needle body into or through the tissue fold at another location adjacent to the originally formed tissue passage. This process may be repeated any number of times to form a continuous or running suture depending upon the desired length of suture and the desired suturing effects.

[0011] Additionally, a gastroscope having a sufficiently small-sized diameter may be introduced into the area by advancing the gastroscope through a lumen defined through the endoscopic device to provide endoscopic visualization of the procedure. Alternatively, a gastroscope may be may be attached or connected to a tubular member disposed externally of the endoscopic device. In another alternative, an imager may be directly integrated into the distal tip of the endoscopic device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Figs. 1A and 1B show a side view and detail view, respectively, of one variation of an endoscopic device for forming and suturing a tissue fold within a hollow body organ.

[0013] Figs. 2A and 2B show side-sectional views of a tissue grasping assembly suitable for use with the endoscopic device of Figs. 1A and 1B.

[0014] Figs. 3A to 3E show side views illustrating one example of a method for forming a tissue fold with the device of Figs. 1A and 1B.

[0015] Fig. 4 shows another variation of the endoscopic device having a rotatable tissue grasping assembly which may be used in creating a continuous stitch in tissue.

[0016] Figs. 5A to 5F show side views illustrating another example of a method for forming and suturing a tissue fold with a continuous running stitch.

[0017] Figs. 6A and 6B show side views of an endoscopic device with alternative variations for endoscopically visualizing a tissue folding and/or suturing procedure.

[0018] Fig. 7 shows a perspective partial view of a resulting tissue fold which was secured via a continuous running stitch.

[0019] Fig. 8A shows a side view of a deployable anchor which may be positioned within a needle body for deployment against a tissue fold.

[0020] Figs. 8B and 8C show one example of how an expandable anchor may be deployed from a needle body passed through a tissue fold.

DETAILED DESCRIPTION OF THE INVENTION

[0021] Various methods and devices for forming and/or securing folds of tissue, e.g., in the gastrointestinal (GI) tract such as the stomach of a patient, are presented herein. Such tissue folds may be formed to treat various conditions, for example, for the treatment of obesity by approximating the walls of a gastrointestinal lumen to narrow the lumen and thereby reduce the area for absorption in the stomach or intestines. Such treatments may be effected via an endoscopic device that engages a tissue wall of the gastrointestinal lumen, creates one or more tissue folds, and secures the tissue fold(s) with tissue anchors and/or suture. The suture is preferably disposed through the muscularis and/or serosa layers of the gastrointestinal tissue, as described in further detail below.

[0022] In operation, a distal tip of the endoscopic device engages the tissue and then approximates the engaged tissue to a proximal position relative to the catheter tip, thereby providing a uniform plication of predetermined size. A needle body detachably or removably positioned within a flexible catheter or launch tube may be deployed from the launch tube such that it passes at least partially within or entirely through the fold formed by the approximated tissue. The needle body may also have a length of suture attached thereto for passage through the tissue fold.

[0023] Once the needle body has been penetrated into or through the tissue fold, it may be detached or released from the endoscopic device. The entire endoscopic device or its tissue engaging assembly may then be rotated relative to the tissue fold while maintaining engagement with the tissue to maneuver the catheter or launch tube to the opposing side of the penetrated tissue fold.

[0024] Formation of a tissue fold may be accomplished using at least two tissue contact areas that are separated by a linear or curvilinear distance, wherein the separation distance between the tissue contact points affects the length and/or depth of the fold. In operation, a

tissue grabbing assembly engages or grasps the tissue wall in its normal state (i.e., non-folded and substantially flat), thus providing a first tissue contact area. The first tissue contact area then is moved to a position proximal of a second tissue contact area to form the tissue fold. The tissue anchor assembly then may be extended across the tissue fold at the second tissue contact area. Optionally, a third tissue contact point may be established such that, upon formation of the tissue fold, the second and third tissue contact areas are disposed on opposing sides of the tissue fold, thereby providing backside stabilization during extension of the anchor assembly across the tissue fold from the second tissue contact area.

[0025] Preferably, the first tissue contact point is used to engage and then stretch or rotate the tissue wall over the second tissue contact point to form the tissue fold. The tissue fold may then be approximated to a position wherein a portion of the tissue fold overlies the second tissue contact point at an orientation that is normal to the tissue fold. A needle body and suture may then be delivered across the tissue fold at or near the second tissue contact point. A description of one or more endoscopic devices which may be utilized to initially form the one or more tissue folds may be seen in further detail in U.S. Pat. App. Serial No. 10/735,030 filed Dec. 12, 2003, which is incorporated herein by reference in its entirety.

[0026] Referring to Fig. 1A, apparatus **10** generally comprises torqueable catheter or tubular member **11** having distal region **12** from which a first and a second flexible tube **13**, **14**, respectively, may extend. First and second tubes **13**, **14** may be interconnected to one another along their lengths and are preferably interconnected near their distal ends in a pivoting manner, as described below. Proximal region **15** of apparatus **10** may be operably connected to handle **16** and actuator **17**, which may actuate the distal region **12** of apparatus **10**. Catheter or tubular member **11** may generally be configured for insertion through a patient's mouth and esophagus into the gastrointestinal lumen. Tissue grabbing assembly **18** is disposed on the distal end of flexible tube **13**, and is operably coupled to actuator **17** via one or more control wires **19** that extend through flexible tube **13**. Tissue grabbing assembly **18** is shown illustratively as a grasper but may be configured in a variety of other alternative tissue grasping assemblies.

[0027] As better illustrated in Fig. 1B, flexible tubes **13** and **14** may be connected via hinge assembly **20** that comprises link **21** attached to flexible tube **13** at pivot point **22** and attached to flexible tube **14** at pivot point **23**. Hinge assembly **20** may be configured to prevent tissue

grabbing assembly **18** from moving more than a predetermined distance relative to distal end **24** of flexible tube **14**.

[0028] Flexible tubes **13** and **14** preferably include bendable sections **25** and **26**, respectively. The bendable sections **25** and **26** may comprise, for example, a plurality of through-wall slots **27** to enhance flexibility of the tube. Preferably, flexible tubes **13** and **14** are made from polymeric materials or biocompatible metals such as Nitinol or stainless steel with an etched or laser-cut slot pattern. The through-wall slots **27** may be configured as a sinusoidal repeating pattern of slots perpendicularly defined relative to the longitudinal axis of tubes **13** and **14**. Alternative flexible patterns will be apparent to those of skill in the art.

[0029] Referring to Figs. 2A and 2B, tissue grabbing assembly **18** may comprises a pair of jaws **28a, 28b** arranged to rotate about pivot point **29** between an open configuration (Fig. 2A) and a closed configuration (Fig. 2B). One or more control wires, shown here as a single control wire **19**, is coupled via pivot point **30** to arms **31a** and **31b**. Arms **31a** and **31b** are in turn pivotally coupled to jaws **28a** and **28b**, respectively, at pivot points **32a** and **32b**. Each of jaws **28a** and **28b** may include sharpened teeth **33** or protrusions disposed near its distal ends to facilitate grasping of the tissue wall of the GI lumen.

[0030] Control wire **19** is coupled to actuator **17** of handle **16** so that translation of the wire **19** within flexible tube **13** causes the jaws **28a, 28b** to open or close. In particular, urging control wire **19** distally (as indicated by arrow **A** in Fig. 2A) moves pivot point **30** distally, thereby forcing the jaws **28a, 28b** to open. Urging control wire **19** proximally (as indicated by arrow **B** in Fig. 2B) moves pivot point **30** proximally, thereby forcing the jaws **28a, 28b** to close together. In alternative variations, tissue grabbing assembly **18** may comprise, e.g., a corkscrew, suction ports, grappling hook or fork, a plurality of needles coupled to the distal end of flexible tube **13**, etc.

[0031] Flexible tube **14** may be affixed to and immovable within catheter **11**, while flexible tube **13** is coupled to catheter **11** via hinge **20**. Accordingly, when control wire **19** is extended in the distal direction, flexible tube **13** is carried in the distal direction. When control wire **19** is retracted in the proximal direction, flexible tube remains stationary until jaws **28a** and **28b** close together, after which further retraction of control wire **19** by moving actuator **17** causes flexible tube **13** to buckle in bendable region **25**, as described below.

[0032] Referring now to Figs. 1 and 3A-3E, operation of apparatus **10** is described for creating a tissue fold in a tissue wall of a GI lumen. In Fig. 3A, distal region **12** of catheter

11 is positioned within a patient's GI lumen transesophageally, and jaws **28a** and **28b** of tissue grabbing assembly **18** are opened by moving actuator **17** to the distal-most position on handle **16**. As depicted in Fig. 3B, actuator **17** may then be moved proximally until the jaws of tissue grabbing assembly **18** engage a portion of tissue wall **W** at contact point **P1**.

[0033] Referring to Fig. 3C, after the tissue wall **W** has been engaged at contact point **P1**, flexible tube **13** is urged proximally within catheter **11** by further proximal retraction of control wire **19** to stretch tissue wall **W** and create tissue fold **F**. During this movement of flexible tube **13**, link **21** of hinge assembly **20** causes tissue grabbing assembly **18** to move from a position distal to distal end **24** of flexible tube **14**, to a position proximal of distal end **24** of flexible tube **14**. Bendable sections **25** and **26** of flexible tubes **13** and **14**, respectively, may accommodate any lateral motion caused by operation of hinge assembly **20**. Advantageously, formation of fold **F** facilitates the penetration of the tissue wall **W** by a needle and subsequent delivery of an anchor assembly or passage of a length of suture, as described hereinafter.

[0034] Referring to Fig. 3D, additional proximal movement of actuator **17** causes flexible tubes **13** and **14** to buckle at bendable sections **25** and **26**. Hinge assembly **20** transmits force applied to flexible tube **13** via control wire **19** and actuator **17** to the distal tip **24**. Preferably, flexible tube **14** is configured so that distal tip **24** contacts, and is generally perpendicular to tissue fold **F** at contact point **P2**. As illustrated in Fig. 3E, once tissue fold **F** is stretched across distal tip **24** of flexible tube **14**, sharpened needle or obturator **34** may be extended from distal tip **24** of flexible tube **14** to pierce all four layers of the tissue wall **W**. Sharpened needle or obturator **34** is inserted via inlet **35** to flexible tube **14** on handle 16 (see Fig. 1A).

[0035] As discussed above, the GI lumen comprises an inner mucosal layer, connective tissue, the muscularis layer and the serosa layer. To obtain a durable purchase, e.g., in performing a stomach reduction procedure, the staples or anchors used to achieve reduction of the GI lumen preferably engage at least the muscularis tissue layer, and more preferably, the serosa layer as well. Advantageously, stretching of tissue fold **F** across distal tip **24** permits an anchor or length of suture to be ejected through both the muscularis and serosa layers, thus enabling durable gastrointestinal tissue approximation.

[0036] As depicted in Fig. 3E, after tissue fold **F** is stretched across distal tip **24** of flexible tube **14** to form contact point **P2** with tissue wall **W**, needle **34** may be extended from distal tip **24** and through tissue fold **F**. Because needle **34** penetrates the tissue wall twice, it exits

within the GI lumen, thus reducing the potential for injury to surrounding organs. Once the needle has penetrated tissue fold **F**, an anchor assembly or length of suture may be ejected through distal tip **24**. The deployment of anchors through needle **34** as well as other variations of the apparatus **10** may be seen in further detail in U.S. Pat. App. Serial No. 10/735,030 which has been incorporated herein by reference above.

[0037] The apparatus **10**, as described above, may be further utilized in suturing the newly formed tissue fold **F** in an interrupted, continuous, or running suture depending upon the length of the newly formed tissue fold and the desired method of tissue fold securement. As shown in the detail assembly view of Fig. 4, jaw assembly **36** and jaw members **28a**, **28b** may be freely rotatable about its longitudinal axis relative to flexible tube **13** and catheter tube **11**, as indicated by the arrow **C**. Moreover, a secondary grasper assembly **37** having a secondary grasper **39** on a distal end of tubular member **38** may be slidably positioned within flexible tube **14**. Grasper **39** may be articulated between an open and close configuration from its proximal end preferably located within handle **16**.

[0038] Grasper **39** may generally comprise a variety of graspers but is preferably configured to grasp and hold onto a needle such as needle body **40**. As shown illustratively in Fig. 4, needle body **40** may generally be configured as a needle having one or two tapered piercing ends on opposing sides of needle body **40**. A suture attachment point **41**, e.g., an eyelet or opening, may be defined along needle body **40** and serve as an attachment point for a length of suture **42**.

[0039] Grasper **39** and flexible tube **38** may define a passage or lumen through which needle body **40** may be passed. Alternatively, grasper **39** and flexible tube **38** may be configured to retain needle body **40** at least partially therein and grasper **39** may be at least partially retracted within flexible tube **14** by the proximal translation of flexible tube **38**. As mentioned above, needle body **40** may be configured in a variety of ways, e.g., a needle body having a piercing tapered end and a balled proximal end to facilitate grasping of the needle body. Other variations of the needle body **40** and grasper **39** may be seen in further detail in U.S. Pat. App. Serial No. 10/989,684 filed July 23, 2004, which is incorporated herein by reference in its entirety.

[0040] In operation, the tissue wall **W** may be grasped and approximated and flexible tube **14** may be curved to align distal tip **24** transversely relative to the tissue fold **F**, as described above. However, in this variation and as shown in Fig. 5A, needle body **40** may be advanced

and pierced into and/or through tissue fold **F** via grasper **39** being advanced distally through flexible tube **14**. The tissue wall **W** is shown in this and the following figures as having at least a mucosa layer **MUC** and an underlying muscularis layer **MUS** as typically found in hollow body organs such as the stomach, although the device and methods are not limited to use in only the GI tract of a patient.

[0041] As seen in Fig. 5B, once needle body **40** has been advanced through or at least partially through tissue fold **F**, needle body **40** may be released by grasper **39** and flexible tube **38** may be retracted from tissue fold **F**. Suture **42** remains attached to needle body **40** and is routed through the tissue passage **43** created by needle body **40**. Suture **42** may be disposed and/or anchored within or proximally of flexible tube **14** or it may simply be ejected therefrom.

[0042] Once grasper **39** has been retracted from tissue fold **F**, the entire apparatus and catheter body may be rotated relative to tissue fold **F** such that flexible tube **14** becomes aligned on the opposite side of tissue fold **F**, i.e., on the side of the tissue where needle body **40** exits tissue fold **F**, as shown in Fig. 5C. In this example, rotatable grasper **36** may keep its grasp on tissue fold **F** to maintain a position of catheter **11** relative to tissue fold **F** and needle body **40** while the device is rotated in the direction as shown by arrow **44**.

[0043] As shown in Fig. 5D, once the device has been realigned, flexible tube **14** may again be manipulated to bend such that distal tip **24** is aligned transversely relative to tissue fold **F**. Flexible tube **38** may then be advanced distally and grasper **39** may be actuated to receive and grasp onto needle body **40**. Once grasper **39** has clamped or grasped onto needle body **40**, flexible tube **38** and/or flexible tube **14** may be pulled proximally to remove needle body **40** from tissue fold **F**, as shown in Fig. 5E. Suture **42** may be seen as passing through tissue fold **F** and desirably through the overlapped muscularis layers.

[0044] While grasper **39** maintains its hold on needle body **40**, the device may again be rotated to realign flexible tube **14** back to the other side of tissue fold **F**, as shown in Fig. 5F by the direction of rotation of arrow **45**. Once flexible tube **14** is desirably positioned, it may again be manipulated distally to align distal tip **24** transversely relative to tissue fold **F** which may again be pierced by advancing needle body **40** into or through tissue fold **F** at another location adjacent to the originally formed tissue passage **42**. While the device and needle body **40** is rotated and re-rotated relative to the tissue fold **F**, suture **42** may be looped about

tissue fold **F** any number of times in a continuous or running suture depending upon the desired length of suture **42** and the desired suturing effects.

[0045] When rotated, the device may be rotated about rotatable grasper **36** as it maintains its hold onto tissue fold **F**. Alternatively, rotatable grasper **36** may release the tissue and the entire device may be relocated along the tissue wall **W** to another position.

[0046] To facilitate the endoscopic suturing of the tissue within the hollow body organ, the area of interest may be visualized through a number of methods. For instance, a laparoscopic camera may be introduced into the area percutaneously to provide a visual image. Alternatively, visualization of the tissue area of interest and of the tissue fold formation and suturing procedure may be visualized endoscopically by positioning an imager, e.g., CCD camera, optical fibers, etc., into the distal end of catheter **11**.

[0047] Alternatively, as shown in Fig. 6A, an endoscope having a sufficiently small-sized diameter, e.g., a gastroscope **47**, may be introduced into the area by advancing the gastroscope **47** through a scope lumen **46** defined through torqueable catheter **11**. Gastroscope **47** may be advanced such that its distal end extends no farther than the distal end of catheter **11** to provide images via an imager **48**, e.g., CCD camera, optical fibers, etc. In another example, the gastroscope **47** may be advanced beyond catheter **11** and proximally adjacent of tissue fold **F**. In such a case, gastroscope **47** is preferably configured to have a manipulatable distal end portion such that articulation of the distal portion of the gastroscope **47** into at least a partially retroflexed configuration is achievable. Having an off-axis imager **48** relative to tissue fold **F** and catheter **11** may provide for triangulation of the image and an improved image of the tissue area.

[0048] Fig. 6B shows an alternative configuration where rather than passing gastroscope **47** within a scope lumen defined through catheter **11**, an external scope lumen **49** may be attached along an outer surface of catheter **11** through a variety of methods, e.g., via a plurality of bands **50**. Gastroscope **47** may then be advanced through external lumen **49** towards tissue fold **F** for imaging.

[0049] As mentioned above, multiple suture loops may be achieved using the devices and methods above depending upon the desired suturing configurations. Fig. 7 shows a partial perspective view of a tissue ridge which may be secured by a continuous running suture loop **51** formed entirely endoscopically. In this particular configuration, suture **42** may be passed through multiple adjacent tissue securement passages **52, 53, 54** with a continuous length of

suture **42**. Other endoscopic suturing configurations are possible and the figure is intended merely to be illustrative of one type of the running sutures which are achievable. The other suturing configurations depend merely upon the desired suturing effects and are not limited by the illustrations shown herein.

[0050] In yet another alternative, the needle body may be configured to carry a tissue anchor within a lumen or channel within the needle body. One example is shown in Fig. 8A, which shows another variation of needle body **55** having a channel defined therein sufficiently sized to retain expandable tissue anchor **56**. Anchor **56** may have suture **42** attached thereto and trailing proximally out from needle body **55**.

[0051] Anchor **56** may comprise any number of various tissue anchors preferably designed for placement against a soft tissue surface. For instance, anchor **56** may comprise an expandable anchor made of a meshed material which allows for reconfiguration between a low-profile delivery configuration, as seen within needle body **55**, and an expanded deployment configuration, as seen in anchor **56'** when unconstrained by needle body **55**. The reconfiguration of the anchor may be effected by a self-expanding metallic alloy material, such as Nitinol, or it may be effected by a meshed polymeric material which configures into an expanded shape against a tissue surface when suture **42** is tensioned. Other examples of various types of tissue anchors which may be utilized are described in further detail in U.S. Pat. App. Serial No. 10/869,472 filed June 15, 2004 and U.S. Pat. App. Serial No. 10/612,170 filed July 1, 2003, both of which are incorporated herein by reference in their entirety.

[0052] An example of how such a deployable anchor may be utilized may be seen in Figs. 8B and 8C. The needle body **55** may be deployed through tissue fold **F** in the same or similar manner as described above by forming tissue fold **F** and passing needle body **55** partially into or through the tissue. As seen in Fig. 8B, with anchor **56** positioned within needle body **55** and suture **42** trailing therefrom, needle body **55** may be grasped by grasping assembly **39** and pulled through the tissue. Once free, anchor **56** may be ejected from needle body **55**, e.g., by pulling suture **42** or actively urging anchor **56** from needle body **55** via an elongate pusher or catheter. Anchor **56'** may then be unconstrained to expand into a deployment configuration and subsequently pulled tight against tissue fold **F** by tensioning suture **42**. Once tensioned, suture **42** may be utilized to secure tissue fold **F** or to hang other objects therefrom.

[0053] Although a number of illustrative variations are described above, it will be apparent to those skilled in the art that various changes and modifications may be made thereto without departing from the scope of the invention. Any of the modifications to endoscopic suturing apparatus and methods may be done in a variety of combinations with one another, as practicable. Any of the combinations or modifications is intended to be within the scope of this invention. It is further intended in the appended claims to cover all such changes and modifications that fall within the true spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. A system for endoscopically suturing a region of tissue, comprising:

an elongate tubular member having a proximal end, a distal end, and a length therebetween;

a tissue engagement device having a distal portion extending from the tubular member distal end and adapted to releasably engage tissue thereto, wherein the distal portion is rotatable about its longitudinal axis relative to the tissue engagement device;

a deployment tubular member having a distal end pivotally movable relative to the elongate tubular member; and

a needle grasper slidably positioned within the deployment tubular member.

2. The system of claim 1 further comprising a needle body and a length of suture depending therefrom, wherein the needle body is removably disposed within the deployment tubular member.

3. The system of claim 2 wherein the needle grasper is adapted to releasably hold the needle body.

4. The system of claim 1 further comprising a needle body which defines a channel therein, wherein the needle body is removably disposed within the deployment tubular member.

5. The system of claim 4 further comprising an expandable tissue anchor for placement within the channel.

6. The system of claim 1 wherein the elongate tubular member comprises a flexible catheter.

7. The system of claim 1 wherein the tissue engagement device comprises a grasper articulatable via its proximal end.

8. The system of claim 1 wherein the tissue engagement device is slidably disposed within a lumen defined through the elongate tubular member.

9. The system of claim 1 wherein the distal portion of the tissue engagement device is adapted to be rotated while maintaining engagement with the tissue.

10. The system of claim 1 wherein the deployment tubular member defines a distal portion adapted to bend relative to the elongate tubular member.

11. The system of claim 1 wherein the deployment tubular member distal end is pivotally connected via a link to the tissue engagement device.

12. The system of claim 1 wherein the needle grasper is adapted to slide through the deployment tubular member while holding a needle body therein.

13. The system of claim 1 further comprising an imager adapted to be positioned proximally of the needle grasper.

14. The system of claim 13 wherein the imager comprises a gastroscope.

15. The system of claim 14 wherein the imager comprises an articulatable distal end.

16. A method for endoscopically suturing a region of tissue, comprising:

endoscopically advancing an elongate tubular member to the region of tissue;

engaging the region of tissue with a tissue engagement device extending from a distal end of the elongate tubular member;

approximating the tissue relative to the elongate tubular member via the tissue engagement device;

deploying a needle body and a length of suture depending therefrom at least partially into or through the tissue from a deployment tubular member extending from the elongate tubular member;

rotating the deployment tubular member about a longitudinal axis of the elongate tubular member; and

grasping the deployed needle body with a needle grasper slidably positioned within the deployment tubular member.

17. The method of claim 16 wherein endoscopically advancing an elongate tubular member comprises advancing the tubular member transesophageally into a stomach.

18. The method of claim 16 wherein engaging the region of tissue comprises temporarily engaging the region of tissue.

19. The method of claim 16 wherein engaging the region of tissue comprises grasping the region of tissue via a grasper.

20. The method of claim 16 wherein approximating the tissue comprises pulling the tissue proximally into a fold via the tissue engagement device.

21. The method of claim 16 further comprising configuring a distal portion of the deployment tubular member transverse to the tissue prior to deploying a needle body.

22. The method of claim 16 wherein deploying a needle body comprises urging the needle body into the tissue via the needle grasper.

23. The method of claim 16 wherein rotating the deployment tubular member comprises rotating a distal portion of the tissue engagement device.

24. The method of claim 23 wherein the distal portion of the tissue engagement device is rotated while maintaining engagement with the tissue.

25. The method of claim 16 wherein grasping the deployed needle body comprises drawing the needle body into deployment tubular member via the needle grasper.

26. The method of claim 16 further comprising rotating the deployment tubular member about the longitudinal axis while holding the needle body.

27. The method of claim 26 further comprising deploying the needle body and the length of suture through the tissue such that the tissue is secure.

28. The method of claim 16 further comprising deploying an expandable anchor from the needle body for placement against the tissue.

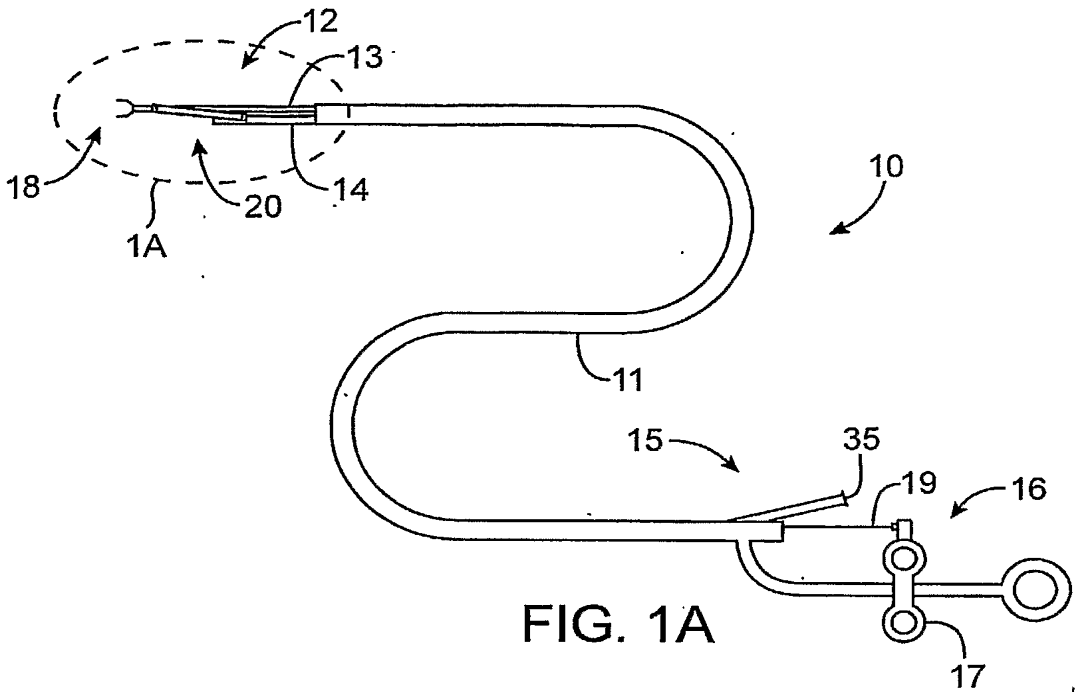

FIG. 1A

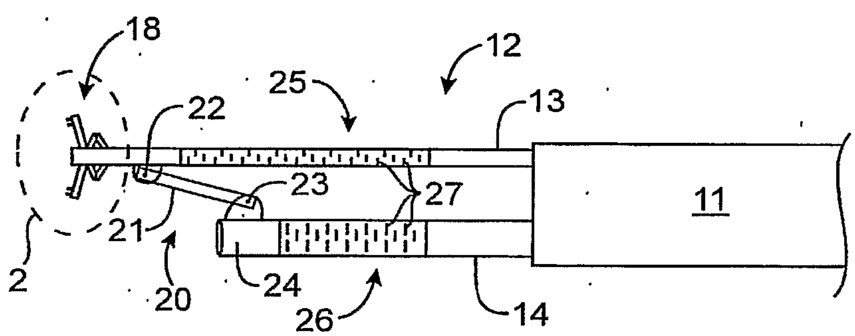

FIG. 1B

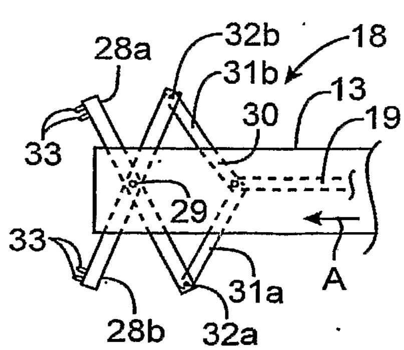

FIG. 2A

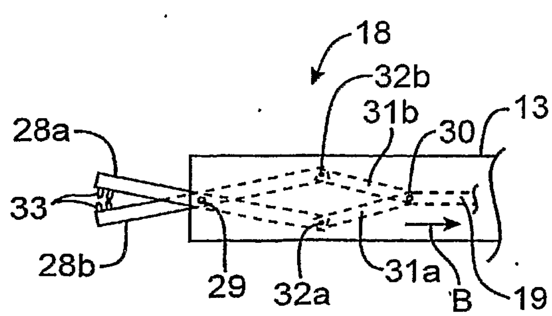

FIG. 2B

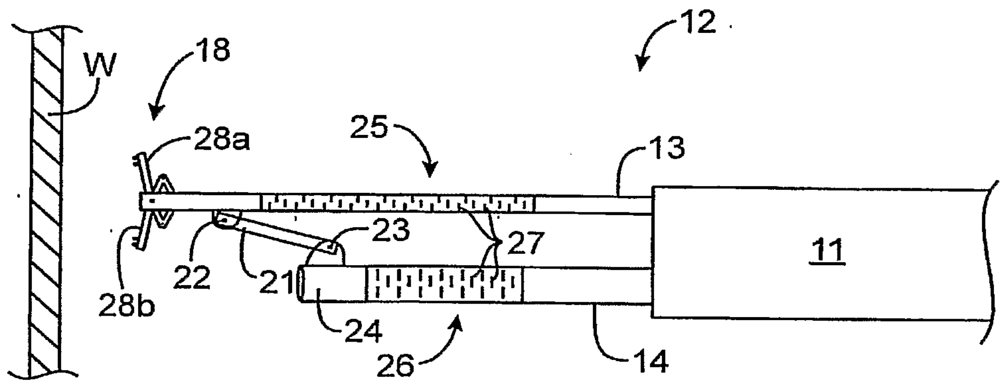

FIG. 3A

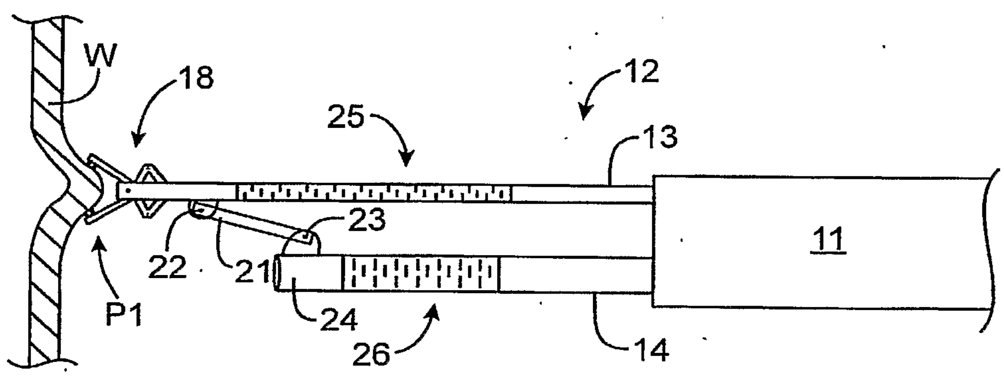

FIG. 3B

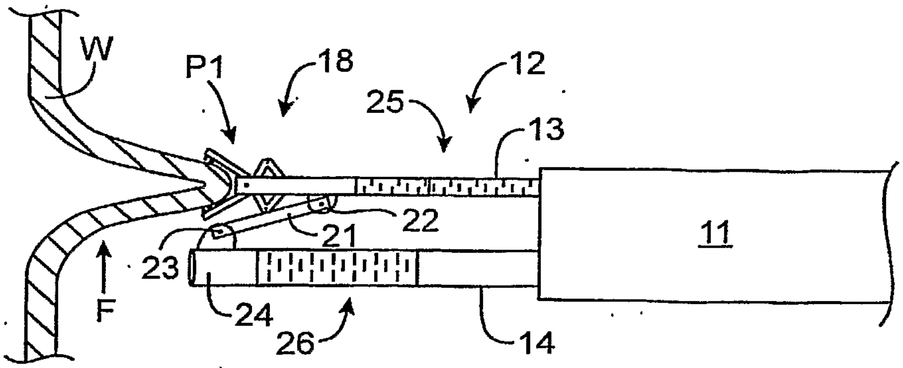

FIG. 3C

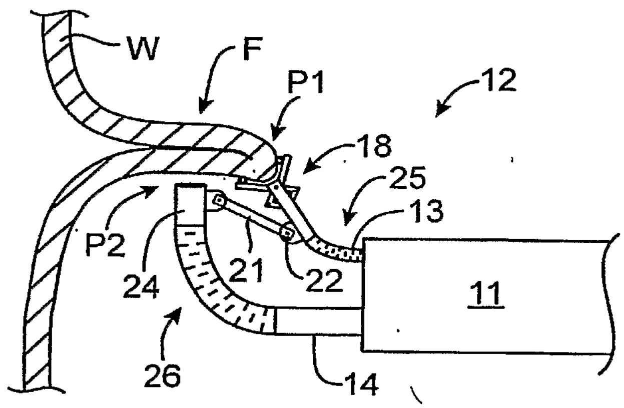
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FIG. 3D

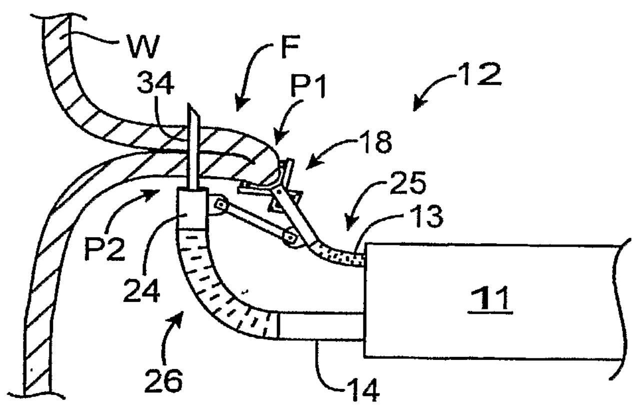
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FIG. 3E

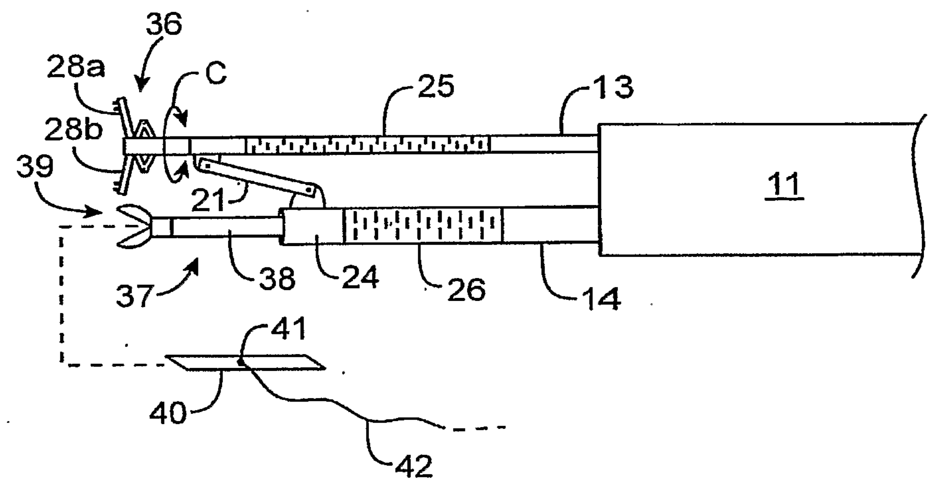

FIG. 4

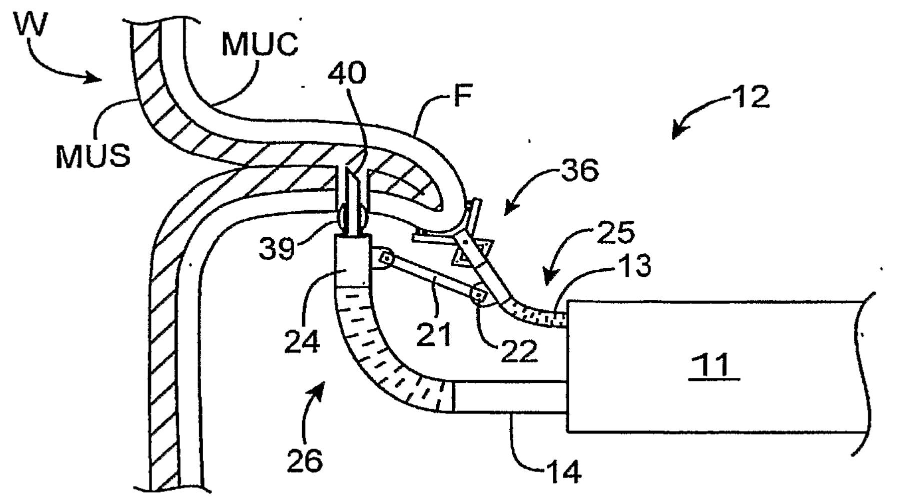

FIG. 5A

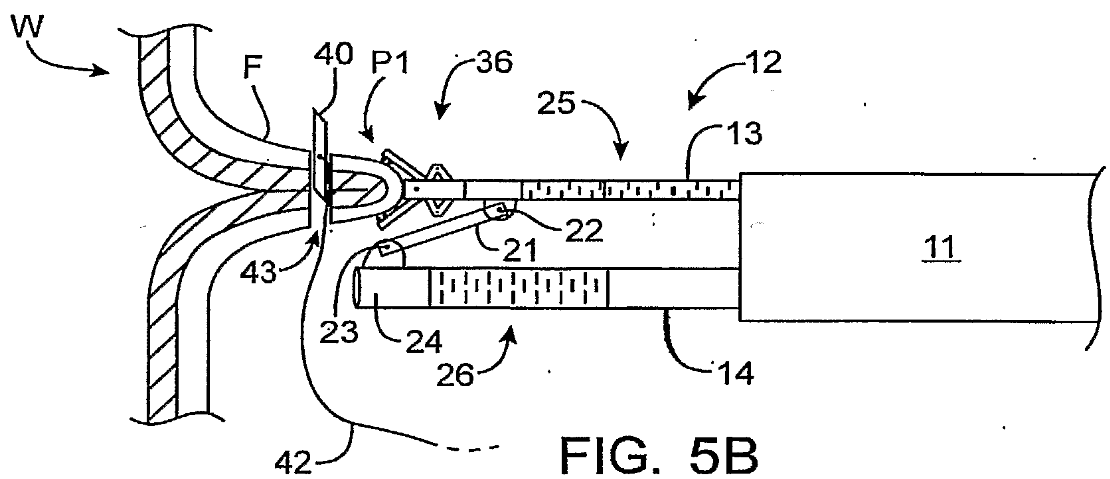

FIG. 5B

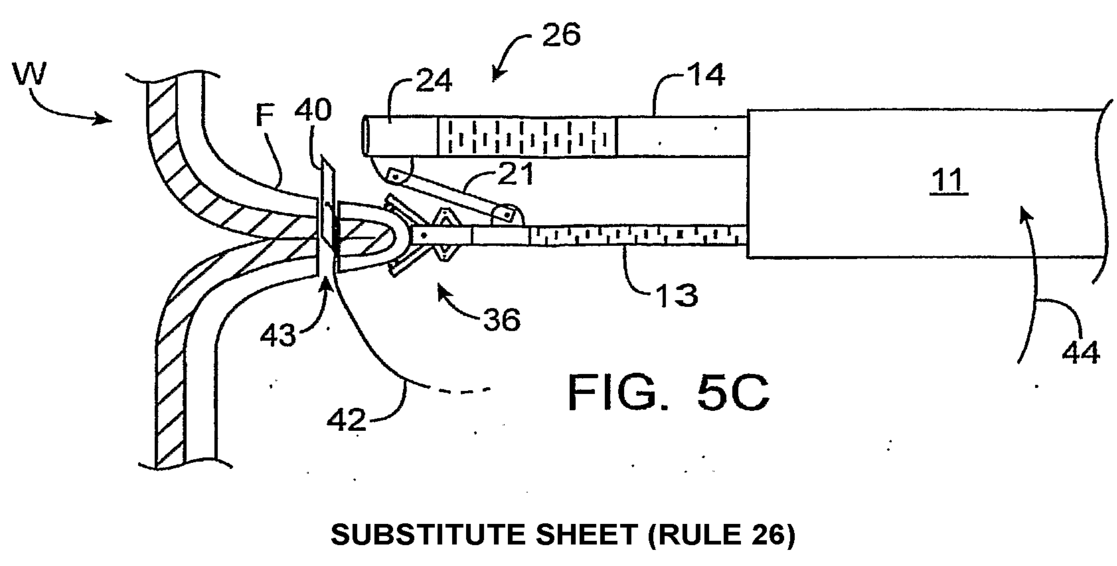

FIG. 5C

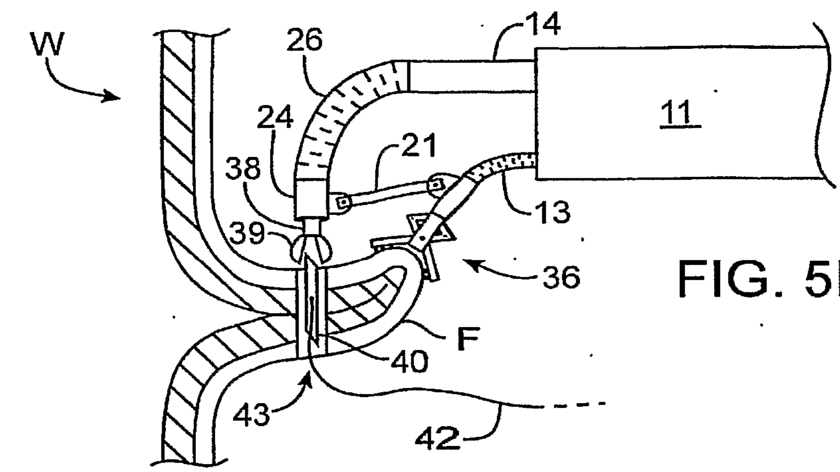

FIG. 5D

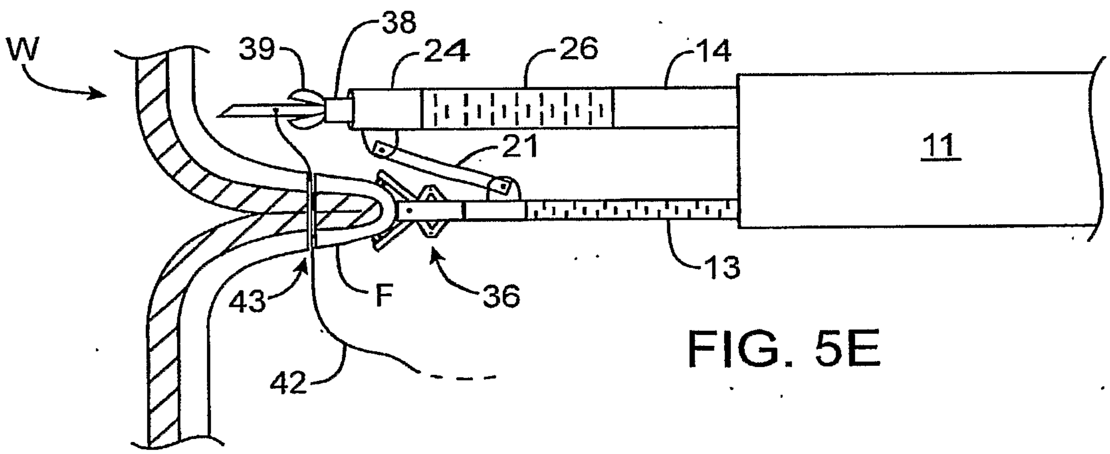

FIG. 5E

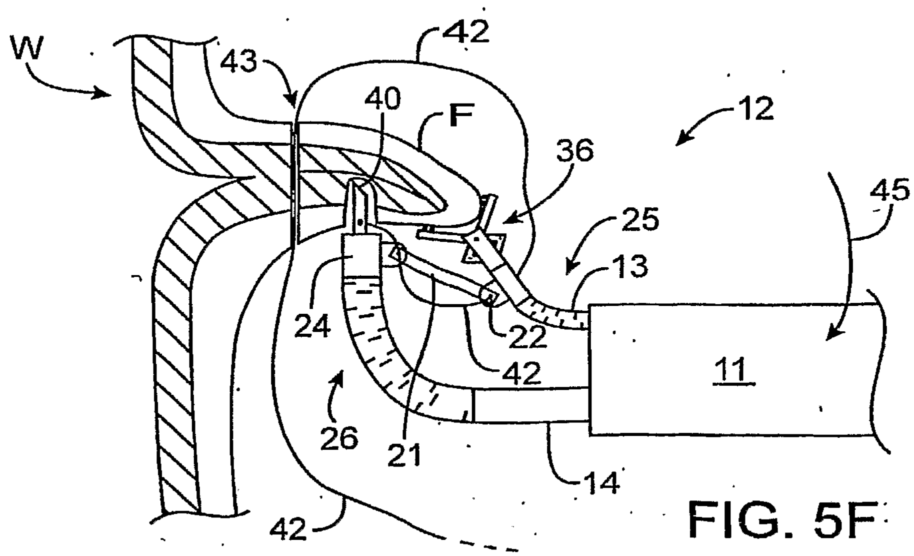

FIG. 5F

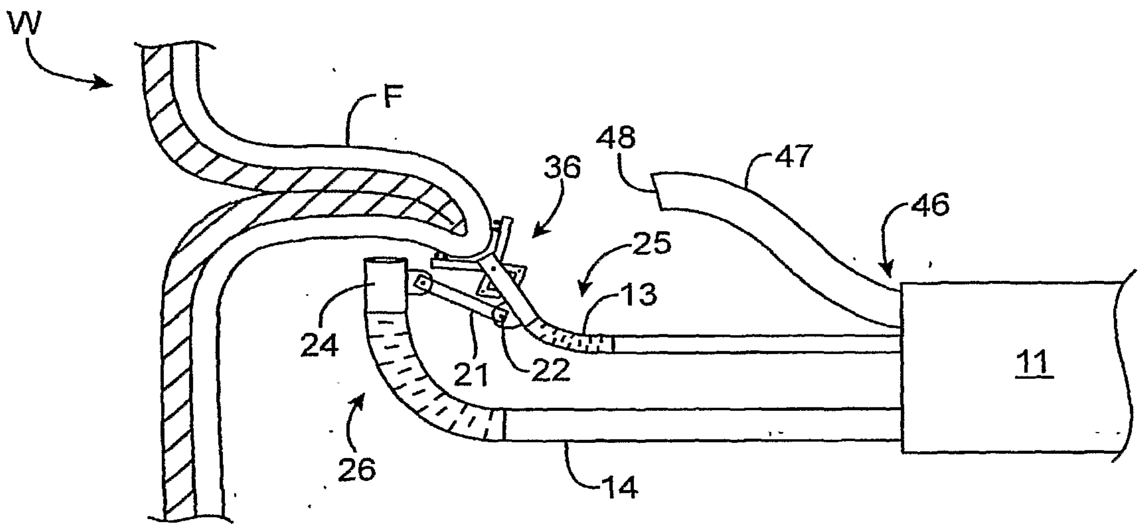
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FIG. 6A

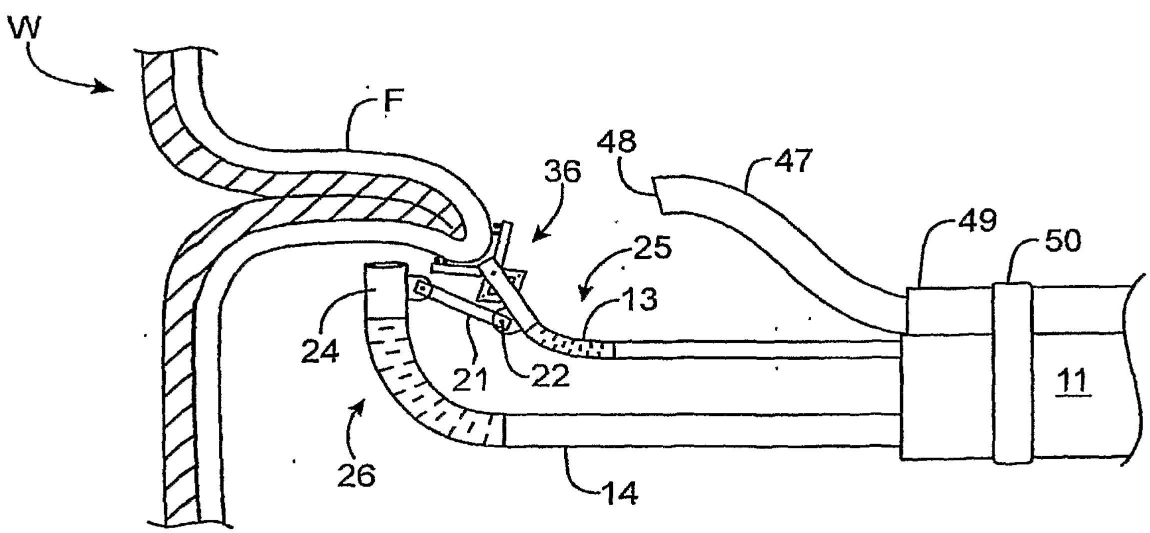
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FIG. 6B

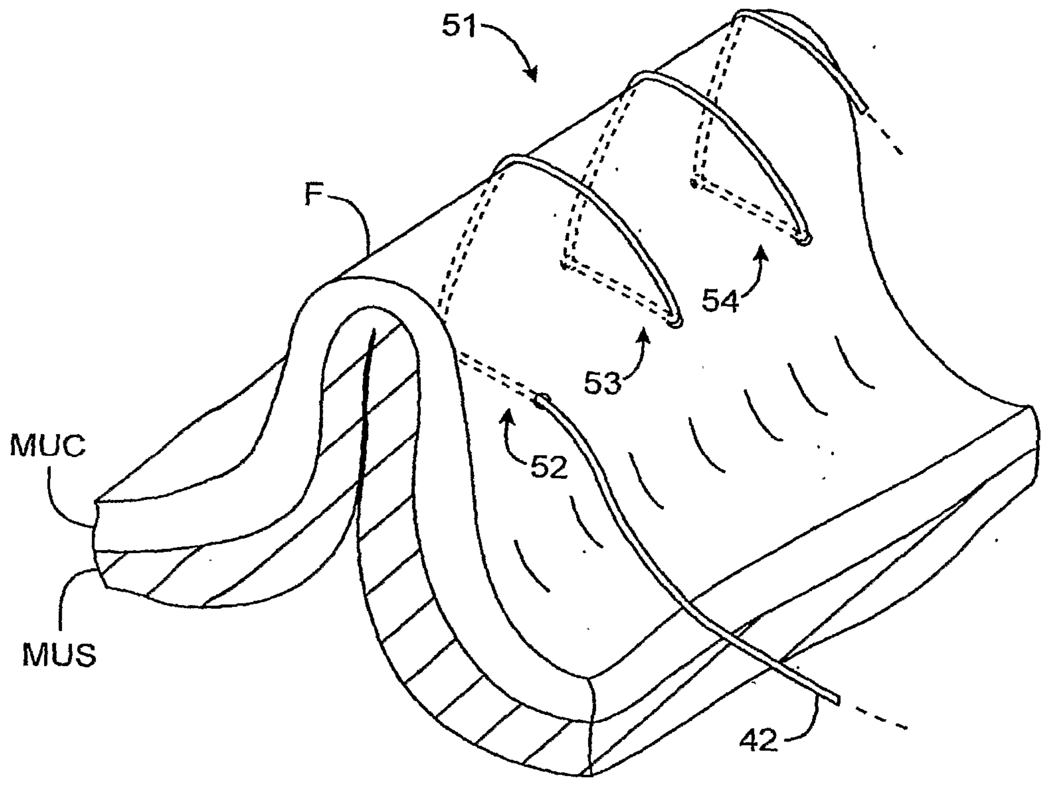

FIG. 7

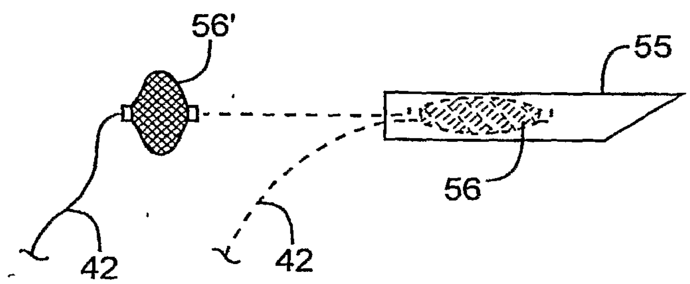

FIG. 8A

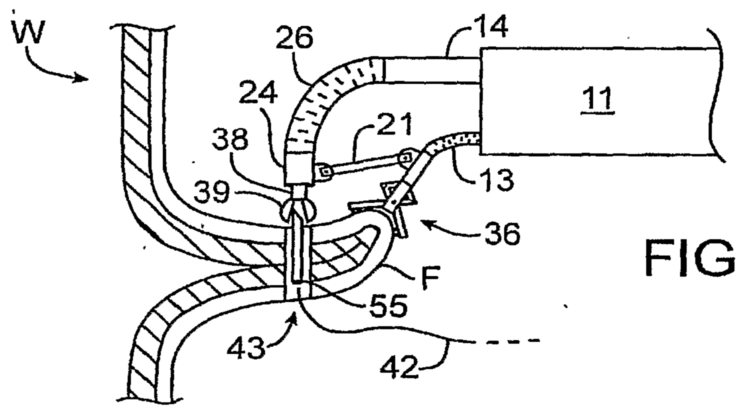

FIG. 8B

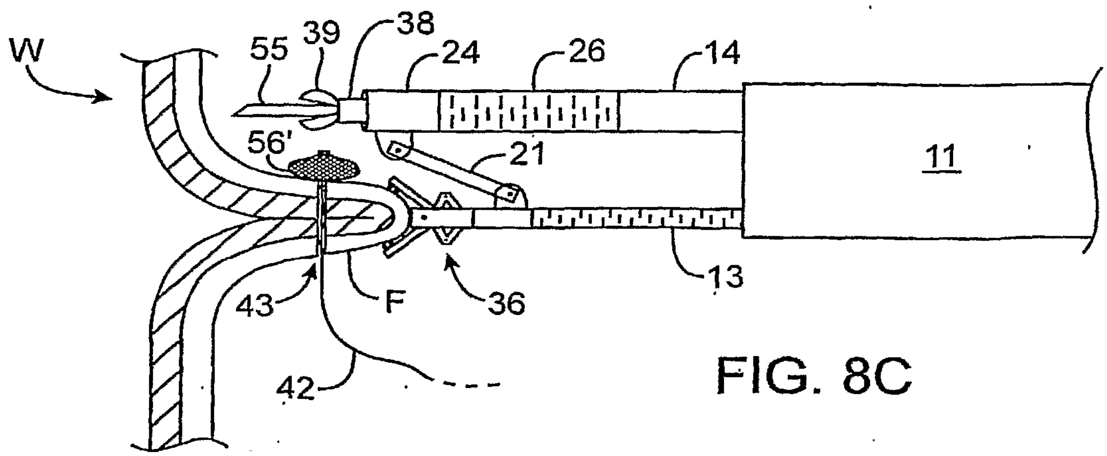

FIG. 8C